K070089

ITEM I

MAR 0 2 2007

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Syntermed, Inc.
Registration No. 1066019
Owner Operator I.D. 9041128
Voice &FAX: (714) 281-1256
Contact person: Kenneth Van Train
Email: vantrain@syntermed.com
Date Summary Prepared: August 3, 2004

2. Medical Device:

The Syntermed Live™ software program should be used for the transfer of medical images and data to a secure server for storage where it can subsequently be accessed, displayed, and processed on any PC connected to the Internet using either proprietary software applications, a DICOM Viewer, or a Web Browser.

3. Medical Device Equivalence:

INTEGRADWeb MPR/MIP™, Reference #: K042313

4. Device Description:

Syntermed Live™ is an Internet based system used to securely access, transfer, display, archive, and process medical images and data generated from a hospital or clinic. The Syntermed Live™ project is involved with the transmission and retrieval of output data files from either Syntermed proprietary applications, DICOM image files, or other medical digital data files to a Syntermed web server so that they can be archived and delivered to Syntermed customers for remote storage and review.

5. Intended Use and Potential Adverse Effect on Health:

The intended use of this program was to provide the physician with a program that would allow them to transfer medical images and data to a secure server for storage where it can subsequently be accessed, displayed, and processed on any PC connected to the Internet using either proprietary software applications, a DICOM Viewer, or a Web Browser. This

program serves merely as a display program to aid in the visual interpretation of a patient's study. This program is used as only a tool to display the patient's medical images. The physician should integrate all of the patients' clinical and diagnostic information prior to making his final interpretation. The expected accuracy of the program can be found in our initial 510(k) submission of the Emory Cardiac Toolbox, K980914. The validation conducted in this submission is listed in Item H, Testing & Validation and this analysis compared the visual interpretation of 30 patient studies using the previous analysis to visual interpretation of the Syntermed Live generated images. The physician should be aware of the accuracy of the initial program when integrating the quantitative results for his final interpretation. Therefore, this program has no direct adverse effect on health since the results represent only a part of the information, which the physician will utilize for his final interpretation. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been several medical device display programs for SPECT and PET marketed in the past which perform similar functions to those performed by the Syntermed Live™ program. The Emory Cardiac Toolbox and NeuroQ are the medical devices which produce the images and quantitative data and Syntermed has filed 510(k) Pre-Market Notifications for these applications (Emory Cardiac Toolbox v2.0, v2.1, v2.6, and NeuroQ v1.0). These programs are all used for the purpose of displaying SPECT and PET tomographic slices and quantitative output which are interpreted by the physician. Syntermed Live™ provides remote access to the data and the ability to display the output of the Syntermed applications using either the applications or Internet Browsers and we believe it is substantially equivalent to the INTEGRADWeb MPR/MIP™ program. To our knowledge there have been no safety problems with the INTEGRADWeb MPR/MIP™ program which has been in the marketplace since September 9, 2004.

7. Conclusions:

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the program has been established in in-house testing and clinical validation studies. Specific details and results concerning the validation of the . Syntermed Live™ program are listed in Item H, Testing & Validation. We contend that the method employed for the development and the final in-house validation results of this medical display software program, . Syntermed Live™, have proven its safety and effectiveness. In our opinion the . Syntermed Live™ program is substantially equivalent to the INTEGRADWeb MPR/MIP™ program which has been cleared for marketing. The . Syntermed Live™ program is intended for the same purpose and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Kenneth F. Van Train
President
Syntermed
245 Owens Drive
ANAHEIM CA 92808

MAR 0 2 2007

Re: K070089
Trade/Device Name: Syntermed Live™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 6, 2007
Received: January 15, 2007

Dear Mr. Van Train:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K070089

DEVICE NAME: Syntermed Live™

INDICATION FOR USE:

The Syntermed Live™ software program should be used for the transfer of medical images and data to a secure server for storage where it can subsequently be accessed, displayed, and processed on any PC connected to the Internet using either proprietary software applications, a DICOM Viewer, or a Web Browser.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070089